OFFICIAL TITLE

BIOAVALABILITY OF ANTIOXIDANT COMPUNDS AND EFFECT ON MARKERS OS INFLAMMATION BY INGESTION OF A *HIBISCUS SABDARIFFA* BEVERAGE WITH GLICEMIC AND INSULINEMIC RESPONSE

LETTER OF INFORMED CONSENT

DATE JANUARY 14TH, 2021

Addressed to: Mexican individuals from the Guadalajara area of the state of Jalisco.

Introduction/Objective

Dear Sir/Madam:

You have been invited to participate in the present research project, which is developed by the Instituto Tecnológico de Tepic and the Instituto Tecnológico y de Estudios Superiores de Occidente (ITESO). The study will be conducted at the Instituto Tecnológico y de Estudios Superiores de Occidente (ITESO).

If you decide to participate in the study, it is important that you consider the following information. Feel free to ask any questions that are not clear to you.

The purpose of the present study is to evaluate a hibiscus, agave fructans and mint-based shot beverage on cholesterol levels and inflammation by means of an acute trial in healthy adults.

We are asking you to participate in this study because you are part of the population of healthy adults in Guadalajara, Jalisco:

Control group of individuals: clinically healthy, non-transplanted individuals. Both genders, aged between 18 and 40 years.

Procedures:

Their participation will consist of blood sampling by venous puncture, 9 samples will be taken, basal (T=0), at 30 min (T=1), at 1h (T=2), 2h (T=4), 3h (T=5), 4h (T=6), 5 h (T=7) and 6h (T=8), after having ingested the drink. And urine for a time of 24 hours, basasl sample (T=0) in a collection bottle, after 6-12 hours and finally 12-24 hours. The samples will be analyzed by the researchers in charge of the project at the ITESO Laboratory in the city of Guadalajara, Jalisco. These analyses will be used to determine lipid profiles (TC, TG, LDL-c and HDL-c), insulin, glucose, inflammation levels (C-Reactive Protein, IL-6 and TNF-a), oxidative stress levels (FRAP, ORAC, LDL-ox) and quantification of compounds (FRAP, ORAC, LDL-ox).

If you agree, the samples will be stored at the ITESO Laboratory. The samples will be labeled with a folio number and not with your name, to ensure the confidentiality of your personal data. The samples will be kept in the laboratory for the duration of the test (if you agree) and after this time they will be properly destroyed.

- The interview and questionnaires will last around (15-20 minutes), with hybrid modality: online questionnaires and face-to-face appointment for sample collection and anthropometric measurements; and will cover several questions about your clinical characteristics, social demographics and general lifestyles, where it will be performed at ITESO.

Benefits:

- You will have an anthropometric evaluation so you can know your body composition.

- You will receive a drink that is not yet available to the public.

- You will have the opportunity to help and be part of a study that could solve other people's health problems in the future.

-You will know your cholesterol levels

You will know your triglyceride levels, LDL-c, HDL-c, glucose level, insulin, HOMA index and you will help to know the potential anti-inflammatory effect that the consumption of the shot drink can have.

Confidentiality: All information provided is strictly confidential, will be used only by the research team of the project and will not be available for any other purpose. The results obtained from this study will be published for scientific purposes, but the confidentiality of the participants will never be violated. The information or evidence obtained will be eliminated after fulfilling the scientific purposes for which this intervention was proposed.

The residence addresses provided, e-mail addresses and telephone numbers will never be disclosed or made available to third parties.

If the requirements are met, the participants will meet by means of a virtual conference prior to the study, where the study will be explained in detail and any doubts will be clarified.

On the day of the study, the informed consent form will be explained to them and their signature will be collected.

In order to comply with the effects of Personal Data Protection under the terms of the Federal Law for the Protection of Personal Data in Possession of Individuals, the data provided by the holder to ITESO will be stored in our databases, under the physical, technical and administrative measures to ensure its correct treatment in accordance with the data protection strategy established by ITESO.

NOTE: at any time during the study, the participant will be free to withdraw his/her consent to participate.

oluntary Participation/Withdrawal: Your participation in this study is completely voluntary. You are free to refuse to participate or to withdraw from the study at any time. Your decision to participate or not in the study will not imply any type of consequence or affect in any way your job or the services of the Instituto Tecnológico y de Estudios Superiores de Occidente (ITESO).

Your participation in this study is absolutely voluntary. You are free to decide which samples you agree to provide or to refuse to participate or to withdraw your participation in the study at any time you wish. You may also request that your samples be withdrawn from the study without any type of consequence, please contact the investigator responsible for the study Dr. Edgar Jair Mendivil Rangel at mendivil@iteso.mx.

Potential Risks/Compensation: This project will be maintained according to what is specified by the Mexican General Law of Health regarding research for health, articles 13º to 17º, which indicate that this type of study is classified as "low risk" or "null". Therefore, no compensation is generated.

Simplified Privacy Notice: The principal investigator of this study, Dr. Edgar Jair Mendivil Rangel, is responsible for the treatment and safekeeping of the personal data you provide us, which will be protected in accordance with the provisions of the General Law for the Protection of Personal Data in Possession of Obligated Subjects. The personal data that we request will be used exclusively for the purposes set forth in this document. You may request the correction of your data or that your data be removed from our databases or withdraw your consent for its use. In any of these cases we ask you to contact the researchers responsible for the project at the following e-mail address mendivil@iteso.mx,

As part of the collaboration of this study, your information will be shared with researchers from the following institution: CONACYT.

If you do not agree to the sharing of your data with these institutions, please let us know by sending a message to the principal investigator at mendivil@iteso.mx,.

Contact numbers: If you have any questions, comments or concerns regarding the project, please contact the researcher responsible for the project: Dr. Edgar Jair Mendivil Rangel from Monday to Friday from 8:00 to 17:00 hrs at mendivil@iteso.mx

If you agree to participate in the study, we will provide you with a copy of this document, which we ask you to sign.

Declaración de la persona que da el consentimiento

- Se me ha leído esta Carta de consentimiento.
- Me han explicado el estudio de investigación incluyendo el objetivo, los posibles riesgos y beneficios, y otros aspectos sobre mi participación en el estudio.
- He podido hacer preguntas relacionadas a mi participación en el estudio, y me han respondido satisfactoriamente mis dudas.

Si usted entiende la información que le hemos dado en este formato, está de acuerdo en participar en este estudio, de manera total o parcial, y también está de acuerdo en permitir que su información de salud sea usada como se describió antes, entonces le pedimos que indique su consentimiento para participar en este estudio.

Registre su nombre y firma en este documento del cual le entregaremos una copia.

PARTICIPANTE:

Nombre: _____

Firma: _____

Fecha/hora _____

Nombre y firma del investigador o persona que obtiene el consentimiento: **Nombre: _____** **Firma: _____** **Fecha/hora _____**